Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

FY2023 Q1
Financial Results Presentation

DAIICHI SANKYO CO., LTD.

Koji Ogawa

Executive Officer, CFO

July 31, 2023

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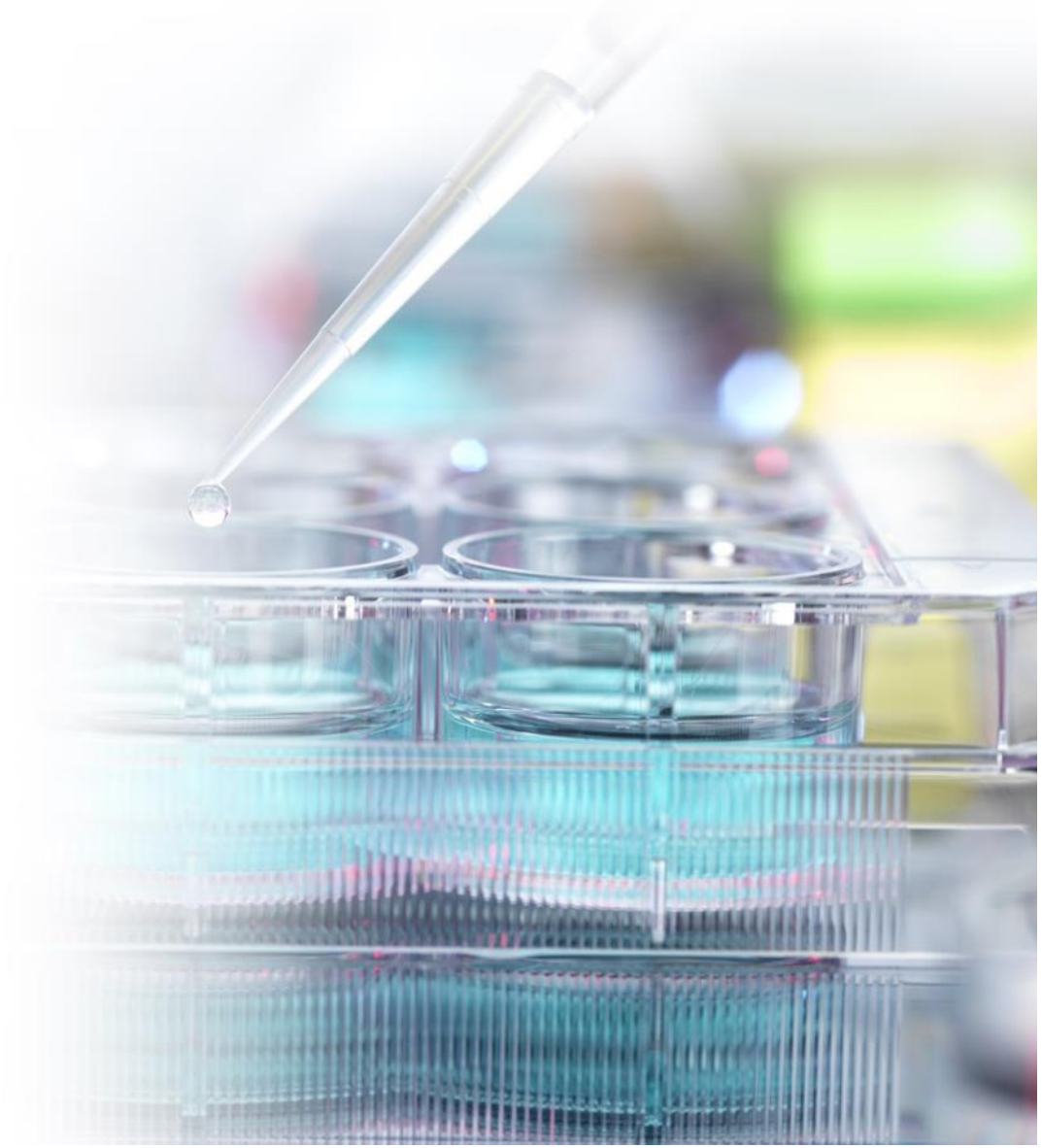
Agenda

1. **FY2023 Q1 Financial Results**
2. Business Update
3. R&D Update
4. Appendix



Overview of FY2023 Q1 Results

(Bn JPY)

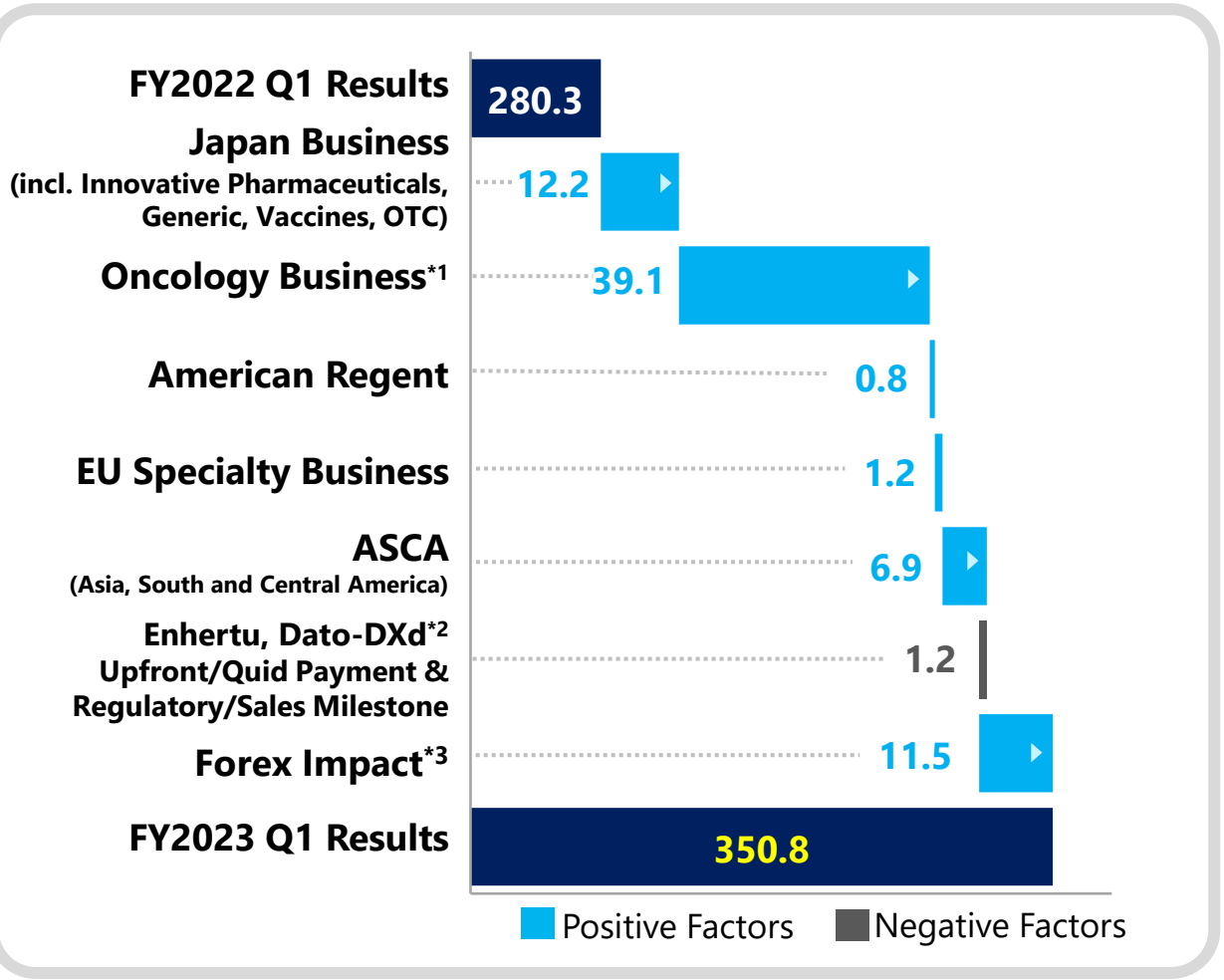
	FY2022 Q1 Results	FY2023 Q1 Results	YoY	
Revenue	**280.3**	**350.8**	+25.2%	**70.5**
Cost of sales*	74.7	93.6		18.9
SG&A expenses*	96.3	135.6		39.3
R&D expenses*	74.9	77.2		2.2
Core operating profit*	**34.4**	**44.5**	+29.4%	**10.1**
Temporary income*	0.0	0.5		0.5
Temporary expenses*	-	0.9		0.9
Operating profit	**34.4**	**44.0**	+28.1%	**9.7**
Profit before tax	**29.4**	**52.1**		**22.7**
Profit attributable to owners of the Company	**18.9**	**57.0**	+202.4%	**38.2**

Currency Rate	USD/JPY	129.57	137.37	+7.80
	EUR/JPY	138.10	149.46	+11.36

*As an indicator of ordinary profitability, "core operating profit" which excludes temporary income and expenses from operating income is disclosed.
Income and expenses related to: sale of fixed assets, restructuring (excluding the sales of pipeline and launched products), impairment, loss compensation, reconciliation, and other non-temporary and material gains and losses are included in the "temporary income and expenses".
Temporary income and expenses are excluded from results and forecast for cost of sales, SG&A expenses and R&D expenses shown in the list above.
The adjustment table from operating profit to core operating profit is stated in the reference data

Revenue

Increased by 70.5 Bn JPY (Increased by 59.0 Bn JPY excl. forex impact)



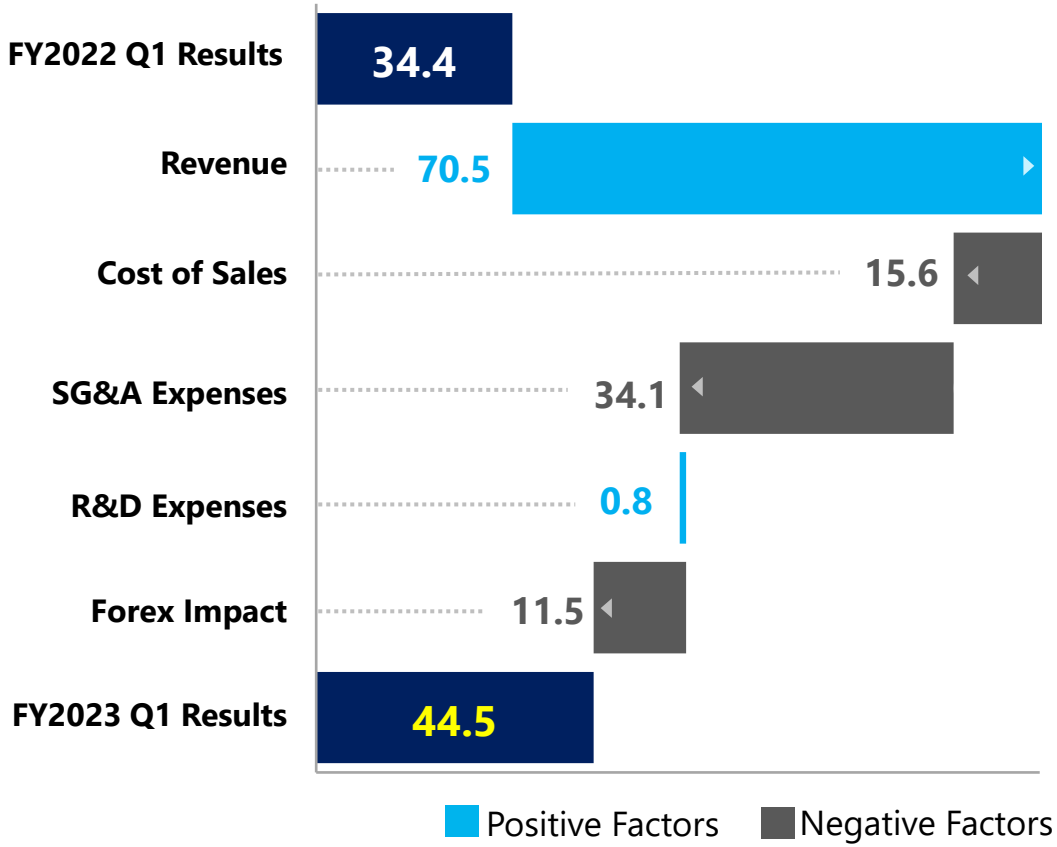
(Bn JPY)

Positive Factors		Negative Factors	
Japan Business Unit			
Lixiana	+2.8		
Tarlige	+2.8		
Enhertu	+1.9		
Efient	+1.3		
Daiichi Sankyo Healthcare	+1.9		
Oncology Business*1 Unit			
Enhertu	+38.7		
American Regent Unit			
Venofer	+2.5	Injectafer	-1.7
EU Specialty Business Unit			
Lixiana	+1.2	Olmesartan	-1.0
Nilemdo/ Nustendi	+1.5		
ASCA (Asia, South and Central America) Business Unit			
Enhertu	+5.5		

*1 Revenue for Daiichi Sankyo, Inc. and Daiichi Sankyo Europe's oncology products
*2 Dato-DXd: Datopotamab deruxtecan (DS-1062)
*3 Forex impact USD: +6.4, EUR : +4.5, ASCA: +0.7

Core Operating Profit

Increased by 10.1 Bn JPY (Increased by 10.0 Bn JPY excl. forex impact)



(Bn JPY)

Revenue +70.5
incl. forex impact of +11.5

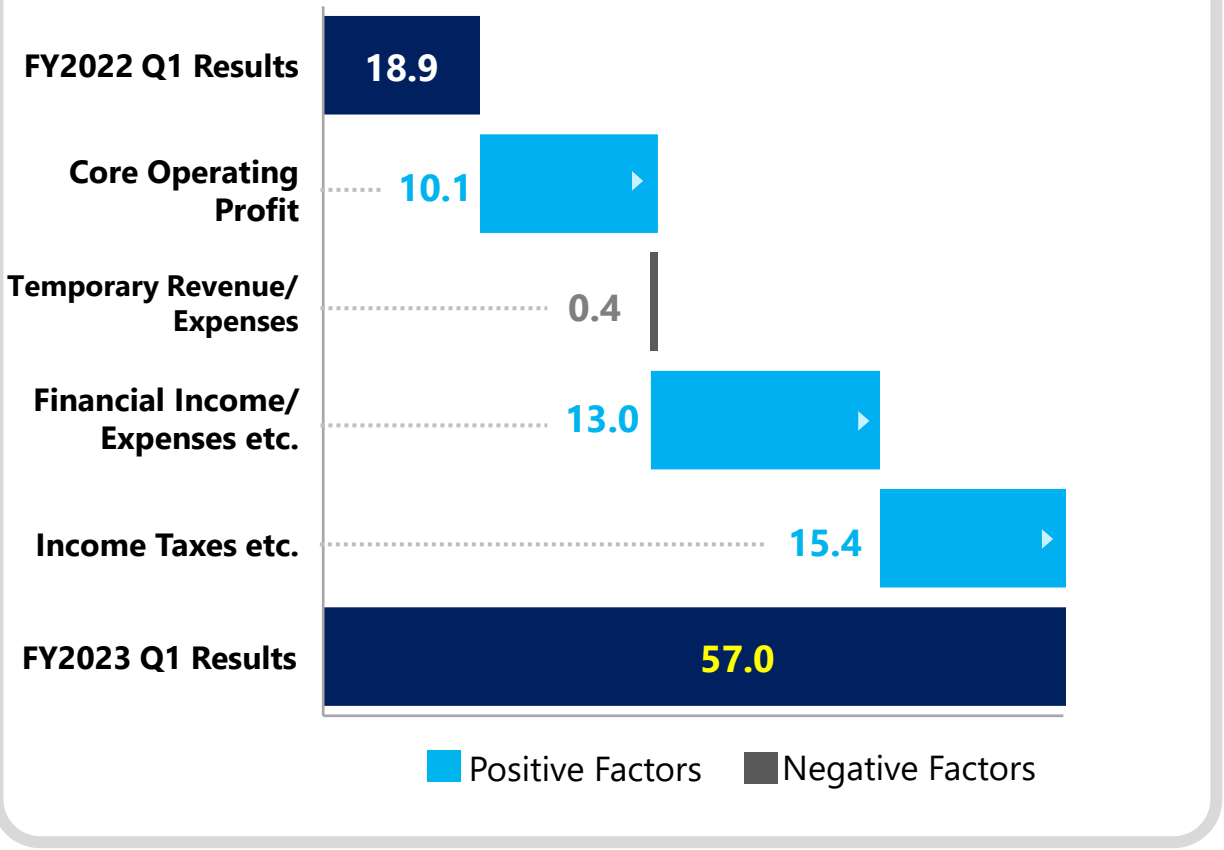
Cost of Sales +15.6
Increase in cost of sales due to the revenue increase

SG&A Expenses +34.1
Increase in expenses related to Enhertu due to an increase in profit share of gross profit with AstraZeneca

Forex Impact +11.5 (Profit Decreased)
Cost of Sales +3.3
SG&A Expenses +5.2
R&D Expenses +3.0

Profit Attributable to Owners of the Company

Increased by 38.2 Bn JPY



(Bn JPY)

Financial Income/Expenses etc. ····· **+13.0（Profit Increased）**

- Improvement in forex gains/losses ····· +4.9
- Improvement in investment securities valuation gains/losses ····· +3.9
- Increase in interest income ····· +2.9

Income Taxes etc. ····· **-15.4**

	FY2022 Q1 Results	FY2023 Q1 Results	YoY
Profit before Tax	29.4	52.1	+22.7
Income Taxes etc.	10.6	-4.9	-15.4
Tax rate	35.9%	-9.4%	-45.3%

Revenue: Business Units (incl. Forex Impact)

(Bn JPY)

	FY2022 Q1 Results	FY2023 Q1 Results	YoY
Japan Business	109.0	119.0	+10.0
Daiichi Sankyo Healthcare	15.3	17.1	+1.9
Oncolgy Business	27.5	70.6	+43.1
Enhertu	26.7	69.4	+42.7
Turalio	0.8	1.2	+0.4
American Regent	47.0	50.7	+3.6
Injectafer	14.1	13.2	-0.9
Venofer	12.4	15.8	+3.4
GE injectables	17.6	18.3	+0.8
EU Specialty Business	37.1	41.5	+4.4
Lixiana	28.6	32.3	+3.7
Nilemdo/Nustendi	1.3	3.0	+1.7
Olmesartan	5.4	4.7	-0.7
ASCA (Asia, South and Central America) Business	31.9	39.5	+7.6

Currency Rate	USD/JPY	129.57	137.37	+7.80
	EUR/JPY	138.10	149.46	+11.36

Revenue: Major Products in Japan

(Bn JPY)

		FY2022 Q1 Results	FY2023 Q1 Results	YoY
Lixiana	anticoagulant	**25.1**	**27.9**	**+2.8**
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	**9.9**	**10.7**	**+0.8**
Tarlige	pain treatment	**8.9**	**11.7**	**+2.8**
Vimpat	anti-epileptic agent	**5.3**	**6.4**	**+1.1**
Ranmark	treatment for bone complications caused by bone metastases from tumors	**4.9**	**5.0**	**+0.0**
Tenelia	type 2 diabetes mellitus treatment	**5.6**	**5.3**	**-0.3**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	**2.4**	**4.4**	**+1.9**
Efient	antiplatelet agent	**4.9**	**6.1**	**+1.3**
Canalia	type 2 diabetes mellitus treatment	**4.1**	**4.1**	**+0.1**
Loxonin	anti-inflammatory analgesic	**4.6**	**4.0**	**-0.6**
Emgality	prophylaxis of migraine attacks	**1.4**	**1.7**	**+0.3**

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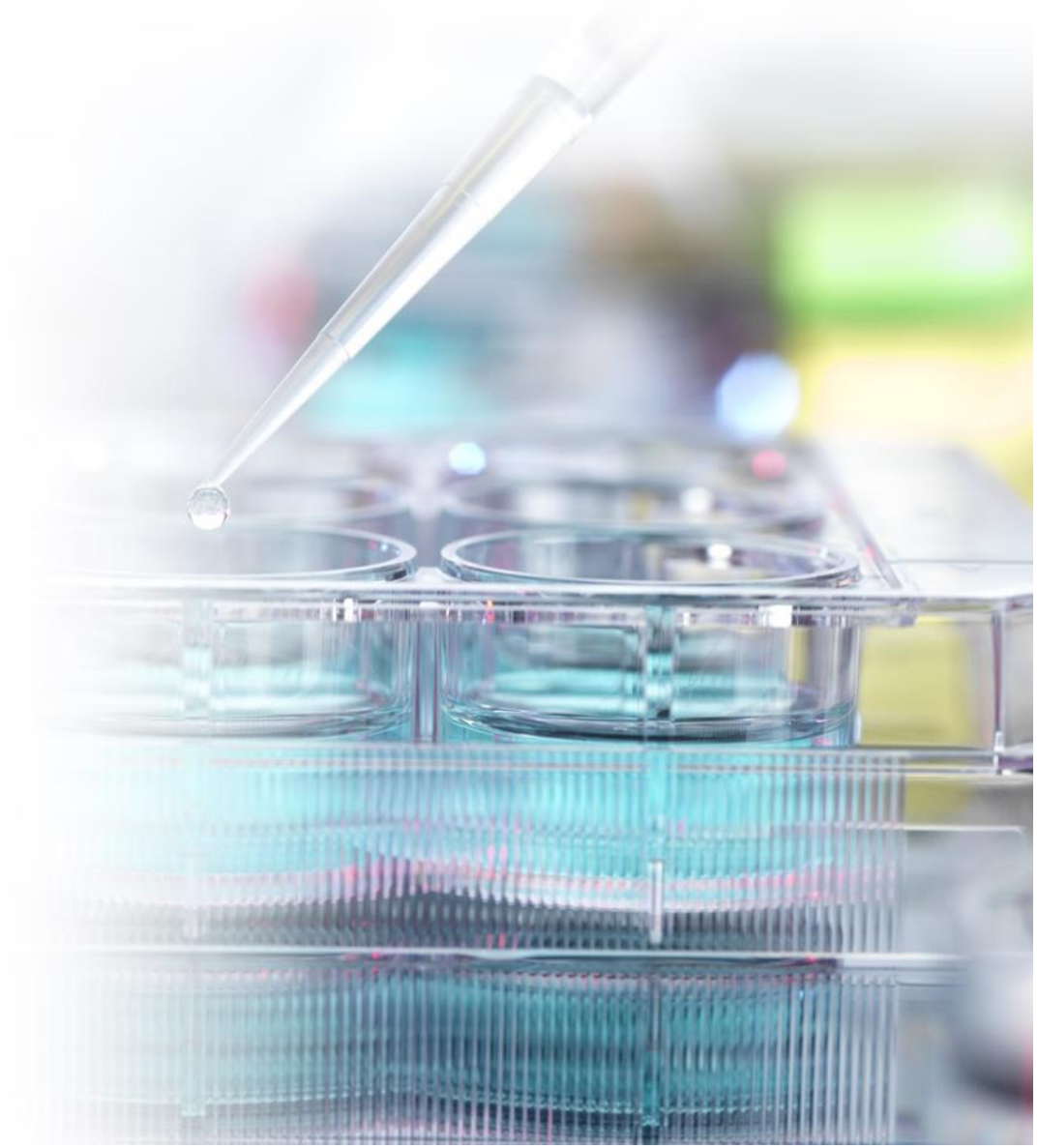


ENHERTU®

Revenue

(Bn JPY)

	FY2023 Q1 Results	YoY	FY2023 Forecast	YoY	<Reference> Total Consideration
Product Sales	81.7	50.4	320.0	112.5	-
Japan	4.4	1.9	19.9	8.2	-
US	51.6	31.5	195.1	50.5	-
Europe	17.8	11.1	75.8	38.8	-
ASCA	8.0	5.8	29.2	15.1	-
Upfront payment	2.5 *1	-	9.8 *1	-	149.0
Regulatory milestone payment	2.1 *1	-1.3	11.6 *1	-15.1	136.3
US HER2+ Breast Cancer 3L	0.2	-	0.9	-	13.7
EU HER2+ Breast Cancer 3L	0.1	-	0.5	-	7.9
US HER2+ Gastric Cancer 2L + 3L	0.2	-	0.8	-	12.1
US HER2+ Breast Cancer 2L	0.2	-2.6	0.9	-2.6	13.1
EU HER2+ Breast Cancer 2L	0.2	0.2	0.7	-2.0	10.1
US HER2-low Breast Cancer (post-chemo)	0.5	0.5	1.8	-5.5	27.7
EU HER2-low Breast Cancer (post-chemo)	0.3	0.3	1.3	-3.9	19.8
EU HER2+ Gastric Cancer 2L	0.1	0.1	0.3	-0.9	4.8
US HER2 Mutant NSCLC 2L	0.3	0.3	1.1	-3.4	17.3
EU HER2 Mutant NSCLC 2L	-	-	3.2	3.2	9.8 *2
Quid related payment	0.3 *1	-	1.1 *1	-	17.2
Sales milestone payment	-	-	26.0 *3	12.8	39.2
Total	86.6	49.2	368.6	110.2	341.7

*1 Revenue recognized in each period

*2 Converted with assumed forex rate for FY2023 of 130 JPY to 1 USD

*3 Milestone of 200Mn USD for achieving annual product sales of 2 Bn USD in co-commercialization territory with AstraZenceca.
(Total amount to be recognized in FY2023)

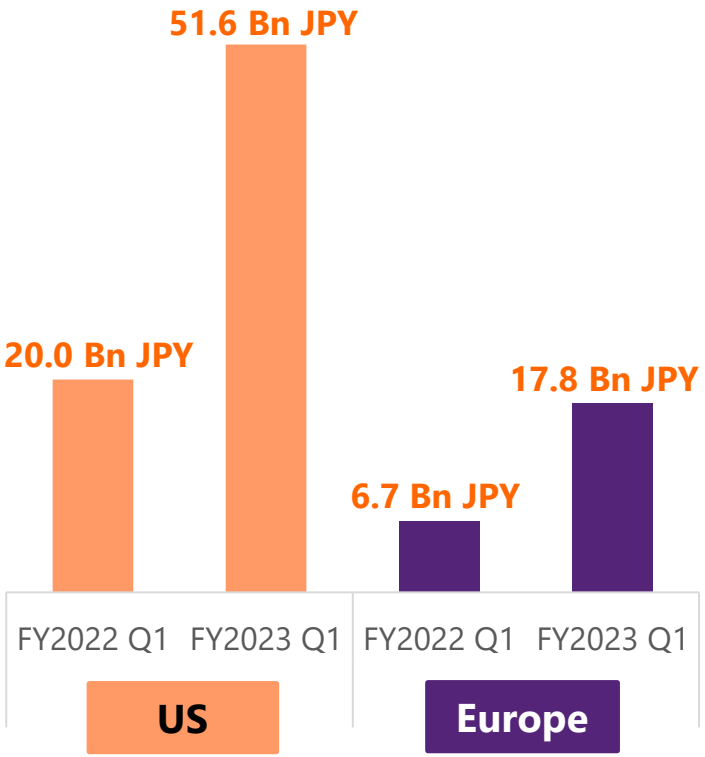
Ref. Total sales milestone payment:
1.75 Bn USD (Max)

ENHERTU®

Performance in Each Region (US, EU)

Global product sales: FY2023 Q1 results 81.7 Bn JPY（YoY +50.4 Bn JPY）FY2023 forecast 320.0 Bn JPY（YoY +112.5 Bn JPY）

ENHERTU® trastuzumab deruxtecan



US

- **Product sales: FY2023Q1 results 51.6 Bn JPY (375 Mn USD) FY2023 forecast 195.1 Bn JPY (1.5 Bn USD)**
- **Indication:** HER2+ mBC 2L+, HER2 low mBC (post-chemo), HER2+ mGC 2L+, HER2 mutant mNSCLC 2L+
- **Market share status**
  - HER2+ mBC 2L: Maintaining No.1 new patient share
  - HER2 low mBC: Maintaining No.1 new patient share and growing further
  - HER2+ mGC 2L: Maintaining No.1 new patient share
  - HER2 mutant mNSCLC 2L: Maintaining No.1 new patient share

Europe

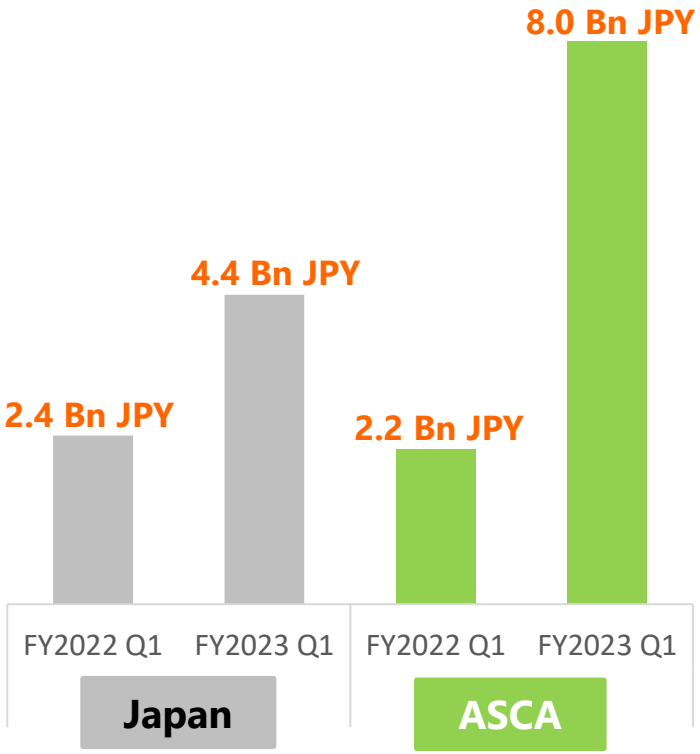
- **Product sales: FY2023Q1 results 17.8 Bn JPY (130 Mn USD) FY2023 forecast 75.8 Bn JPY (583 Mn USD)**
- **Indication**: HER2+ mBC 2L+, HER2 low mBC (post-chemo), HER2+ mGC 2L+
- **Market share status**
  - HER2+ mBC 2L: Maintaining No.1 new patient share in France, Germany and Spain
  - HER2 low mBC : Achieved No.1 new patient share in France and Germany
- **Other progress**
  - Launched in Italy (Jul. 2023)

ENHERTU®

Performance in Each Region (Japan, ASCA)

Global product sales: FY2023 Q1 results 81.7 Bn JPY（YoY +50.4 Bn JPY）FY2023 forecast 320.0 Bn JPY（YoY +112.5 Bn JPY）

ENHERTU® trastuzumab deruxtecan



Japan

- **Product sales: FY2023Q1 results 4.4 Bn JPY FY2023 forecast 19.9 Bn JPY**
- **Indication:** HER2+ mBC 2L+, HER2 low mBC (post-chemo), HER2+ mGC 3L
- **Market share status**
  - HER2+ mBC 2L: Achieved No.1 new patient share
  - HER2 low mBC: Steady uptake in capturing new patient share
  - HER2+ mGC 3L: Maintaining No.1 new patient share

ASCA

- **Product sales: FY2023Q1 results 8.0 Bn JPY FY2023 forecast 29.2 Bn JPY**
- **Indication:** HER2+ mBC 2L+, HER2 low mBC (post-chemo), HER2+ mGC 3L
- **Market share status**
  - Sales growing in Brazil, Hong Kong and Taiwan
- **Other progress**
  - China: Launched for HER2+ mBC 2L (Jun. 2023), Approved for HER2 low mBC (post-chemo) and started promotion (Jul. 2023)

Initiatives Related to Profit Growth for Current Business and Products in Japan

Enhance product portfolio

◆ **VANFLYTA®　Anti-Cancer Agent /FLT3 Inhibitor**

➢ **Obtained partial change approval for acute myeloid leukemia (AML)** 1L therapy in May 2023

Changed from "relapsed/refractory *FLT3*-ITD positive AML" to "*FLT3*-ITD positive AML"

◆ **TARLIGE® Orally Disintegrating Tablet**

Pain Treatment

➢ **Launched** in May 2023

Enhance transformation into a profit structure focused on patented drugs

◆ **Stock Transfer of DAIICHI SANKYO ESPHA CO., LTD. (Concluded an agreement in May 2023)**

➢ Transferee: Qol Holdings Co., Ltd.

➢ Consideration for transfer: 25.0 Bn JPY

➢ Date of transfer (planned) :
October 1, 2023 (30% of the shares held by the Company), April 1, 2024 (21% of the shares held by the Company)
※ The date of execution of the transfer of the remaining 49% of the Company's shares will be determined by separate negotiation.

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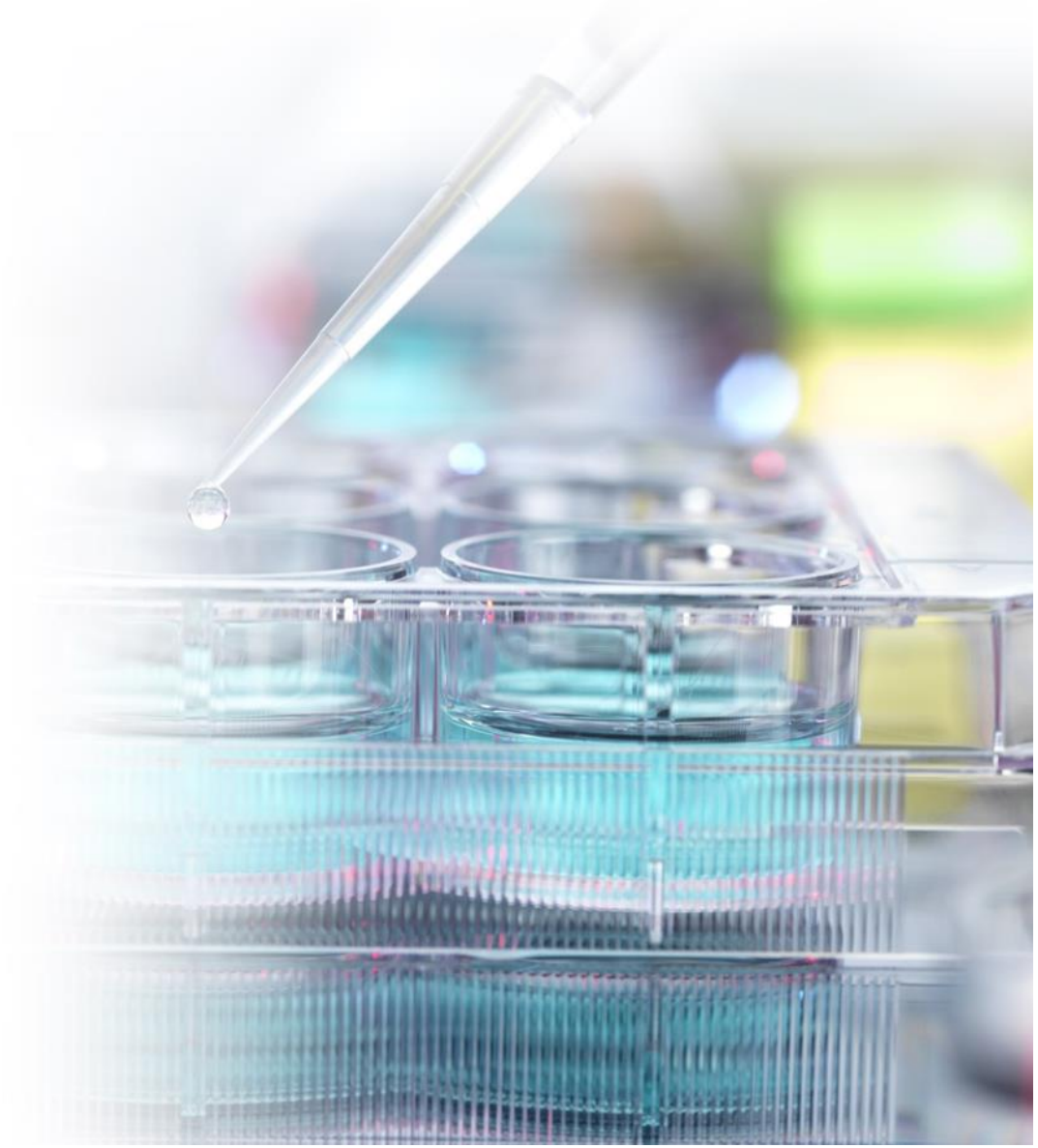
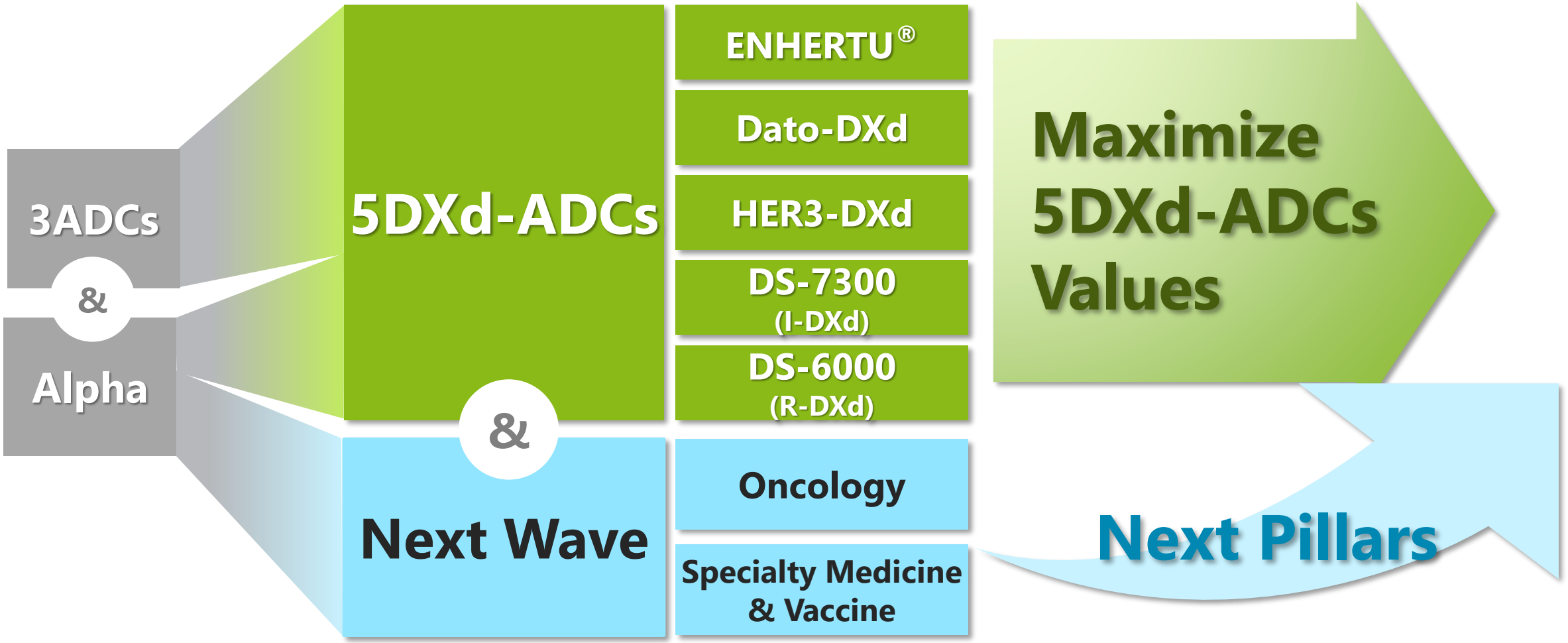


5DXd-ADCs Update

Next Wave Update

News Flow

From “3 and Alpha” to “5DXd-ADCs and Next Wave”



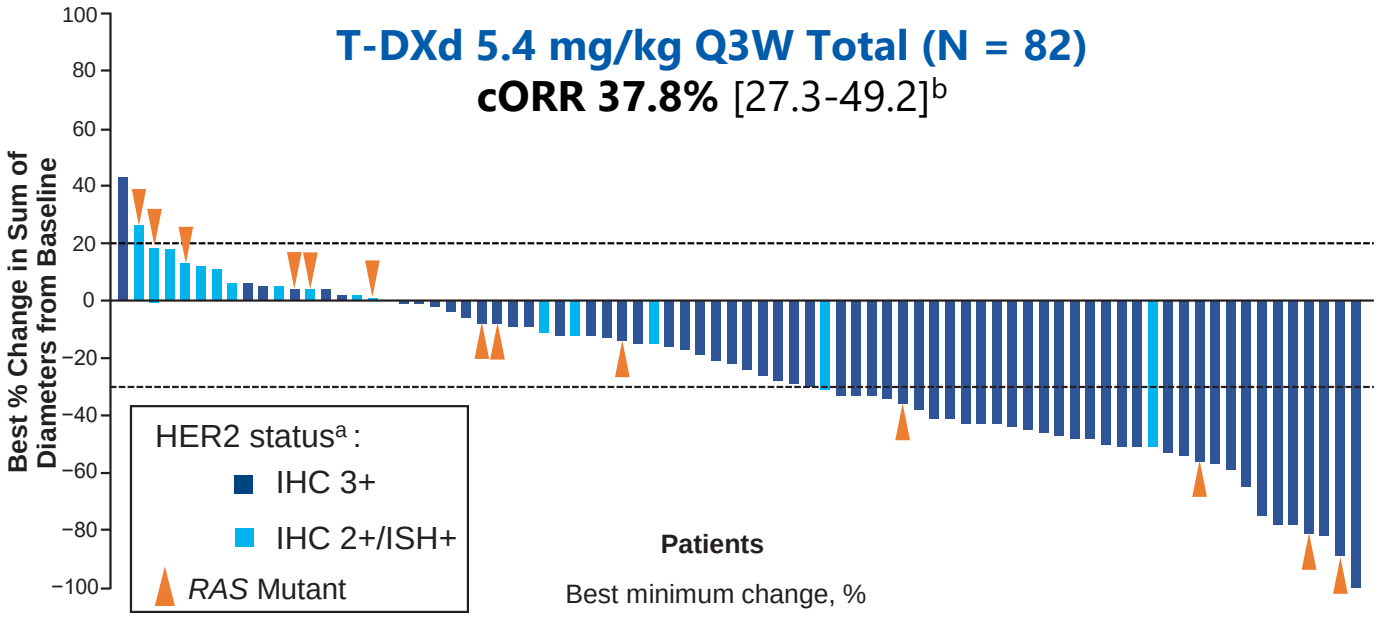
ENHERTU® : trastuzumab deruxtecan (International Nonproprietary Name: INN), T-DXd, DS-8201 (HER2-directed ADC), **Dato-DXd**: datopotamab deruxtecan (INN), DS-1062 (TROP2-directed ADC), **HER3-DXd**: patritumab deruxtecan (INN), U3-1402 (HER3-directed ADC), **DS-7300**: ifinatamab deruxtecan, I-DXd (B7-H3-directed ADC), **DS-6000**: raludotatug deruxtecan, R-DXd（CDH6-directed ADC）

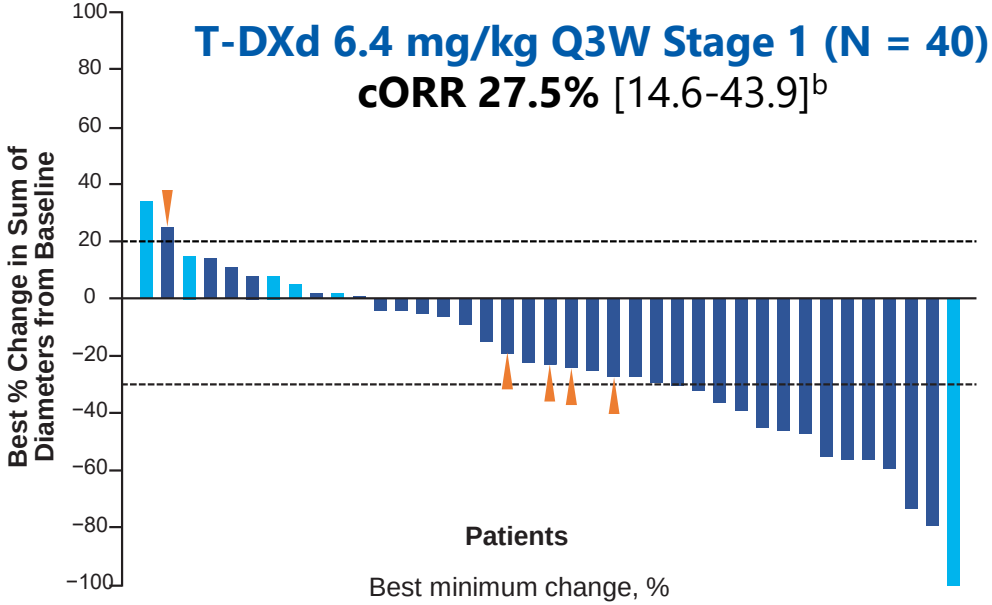
Promising antitumor activity in HER2+ mCRC patients

DESTINY-CRC02 study (ASCO 2023)

Daiichi-Sankyo

DESTINY-CRC02 study suggests 5.4 mg/kg is the optimal dose





- Both doses evaluated confirmed the promising antitumor activity
- Antitumor activity (ORR) in patients with and without RAS mutation at the 5.4 mg/kg dose
- The most common adverse events seen with ENHERTU® in this study were nausea, fatigue, neutropenia, anemia comparable to the known profile of T-DXd
- There was no grade ≥3 ILD/pneumonitis cases in the 5.4 mg/kg arm
- Efficacy and safety profile of both cohorts favors the 5.4 mg/kg dose

[a] HER2 status was assessed by central laboratory. [b] 95% confidence interval. cORR: confirmed objective response rate, IHC: immunohistochemistry, ILD: interstitial lung disease, ISH: in situ hybridization, mCRC: metastatic colorectal cancer, Q3W: every 3 weeks, T-DXd: trastuzumab deruxtecan, TEAE: treatment emergent adverse events

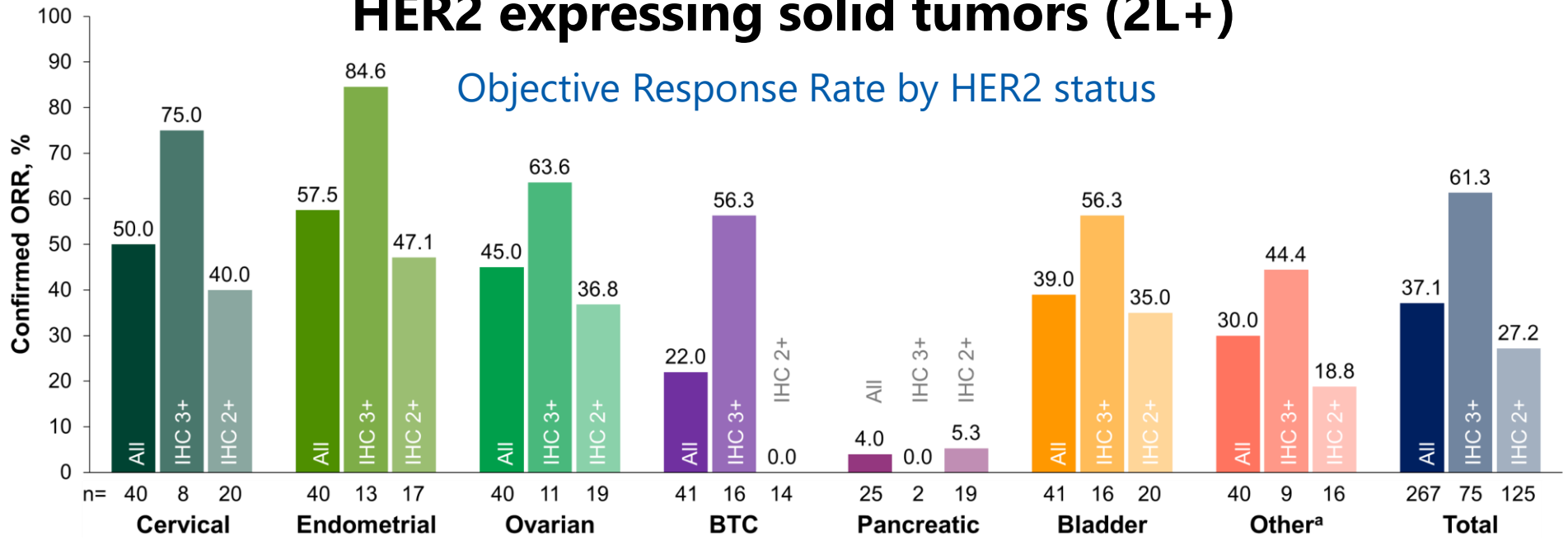
ENHERTU®

Potential new treatment option for HER2 expressing solid tumors

DESTINY-PanTumor02 study (ASCO 2023)

Daiichi-Sankyo

Demonstrated clinically meaningful activity across a broad range of HER2 expressing solid tumors (2L+)



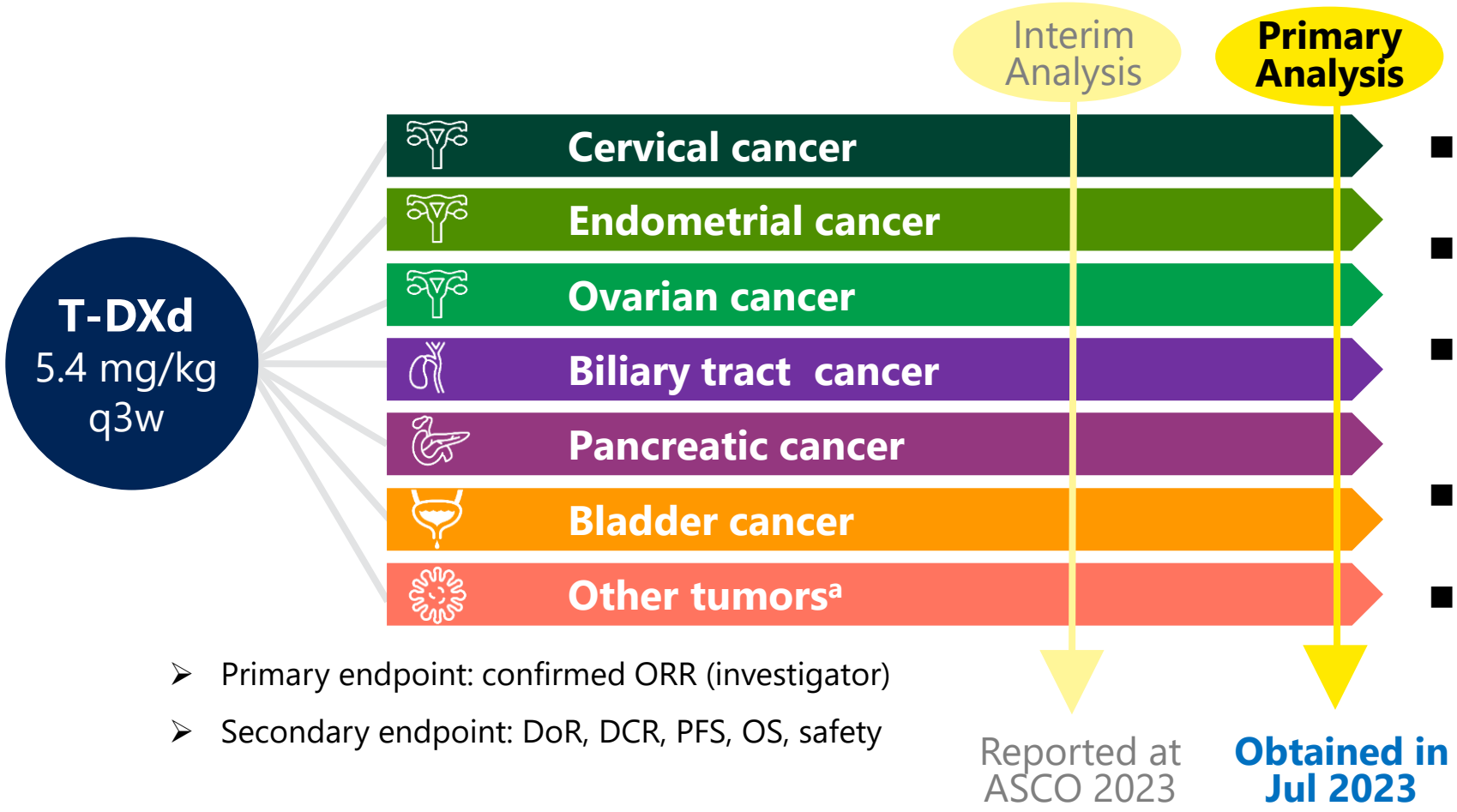
	All patients (N=99)	IHC 3+ (n=46)	IHC 2+ (n=34)
Median DOR, months (95% CI)	11.8 (9.8–NE)	22.1 (9.3–NE)	9.8 (4.2–12.6)

- ORR: 37.1% in all patients (n=267) and 61.3% in patients with IHC 3+ (n=75)
- DoR: median DoR 11.8 months in all patients responded (n=99) and 22.1 months in patients with IHC 3+ (n=46)
- Most common adverse events of ENHERTU® in this study were neutropenia, anemia, fatigue, nausea, thrombocytopenia which were comparable to the known profile seen with T-DXd
- Majority of ILD/pneumonitis events were grade 1 or 2; one grade 3 event and one grade 5 event were observed

[a] Analysis of DoR was performed in patients with objective response [b] Responses in extramammary Paget's disease, head and neck cancer, oropharyngeal neoplasm, and salivary gland cancer.
BTC: biliary tract cancer, CI: confidence interval, DoR: duration of response, IHC: immunohistochemistry, ILD: interstitial lung disease, NE: non-estimable; ORR, objective response rate.

Primary analysis of DESTINY-PanTumor02 study

TLR from the primary analysis was acquired in Jul 2023



- Primary endpoint: confirmed ORR (investigator)
- Secondary endpoint: DoR, DCR, PFS, OS, safety

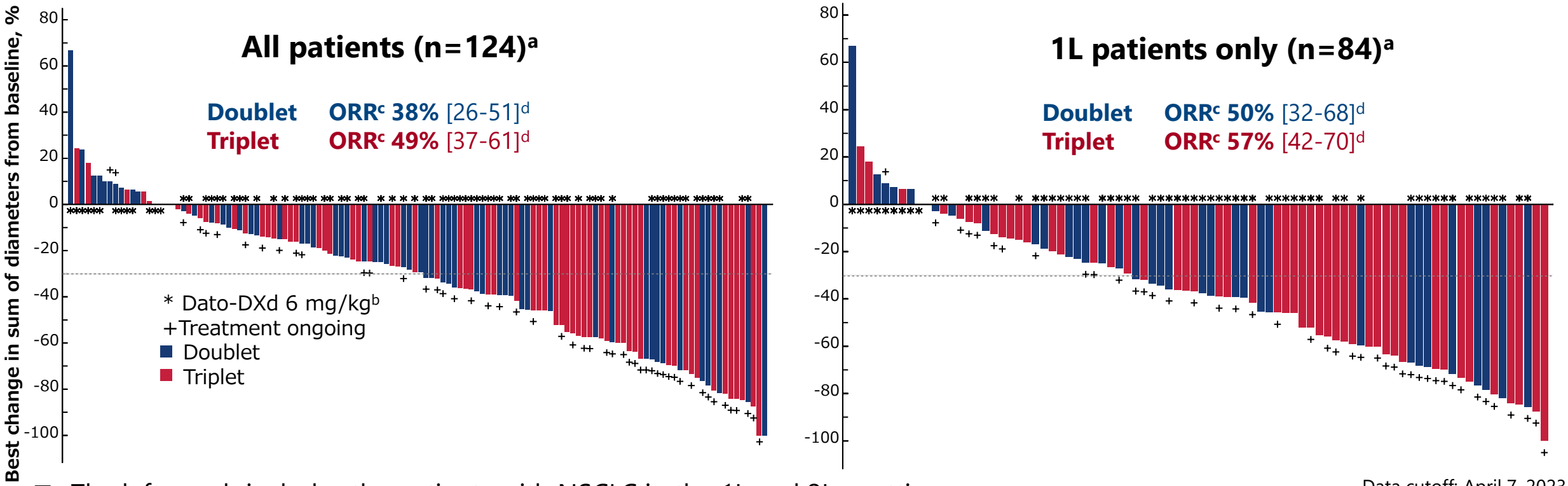
- Continued to show **durable responses for ORR and DoR**
- Demonstrated **clinically meaningful PFS and OS** results
- ILD rates and severity were consistent with those observed in other trials of ENHERTU.
- Data will be presented at an upcoming medical meeting
- Discussions with health authorities are ongoing

[a] Patients with tumors that express HER2, excluding tumors in the tumor-specific cohorts, and breast cancer, non-small cell lung cancer, gastric cancer, and colorectal cancer.
ASCO: American Society of Clinical Oncology, DCR: disease control rate, DoR: duration of response, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, q3w: every 3 weeks, T-DXd: trastuzumab deruxtecan

Encouraging Combination Data in 1L NSCLC

TROPION-Lung02 study（ASCO 2023）

Dato-DXd + Pembrolizumab (Doublet) and additional platinum chemotherapy (Triplet) demonstrated encouraging antitumor activity



Data cutoff: April 7, 2023

- The left graph includes the patients with NSCLC in the 1L and 2L+ settings
- The most common adverse events of Dato-DXd in this study were stomatitis, nausea, anemia, fatigue which were comparable to the known profile of Dato-DXd
- Observed stomatitis and ILD/pneumonitis as AESI, predominantly grade 1 or 2 (no grade 4 or 5 ILD/pneumonitis observed)

[a] Patients with no baseline target lesions or no postbaseline tumor assessments were excluded from the waterfall plots. [b] Planned dose level. [c] Responses pending confirmation. [d] 95% confidence interval

1L: first line, AESI: adverse events of special interest, ASCO: American Society of Clinical Oncology, CI: confidence interval, ILD: interstitial lung disease, NSCLC: non small cell lung cancer, ORR: objective response rate, TEAE: treatment emergent adverse events

Dato-DXd Path for establishing 2L/3L treatment in NSCLC

TROPION-Lung01 study

Disclosed TLR in July 2023

Advanced or metastatic NSCLC 2L/3L

N = 600

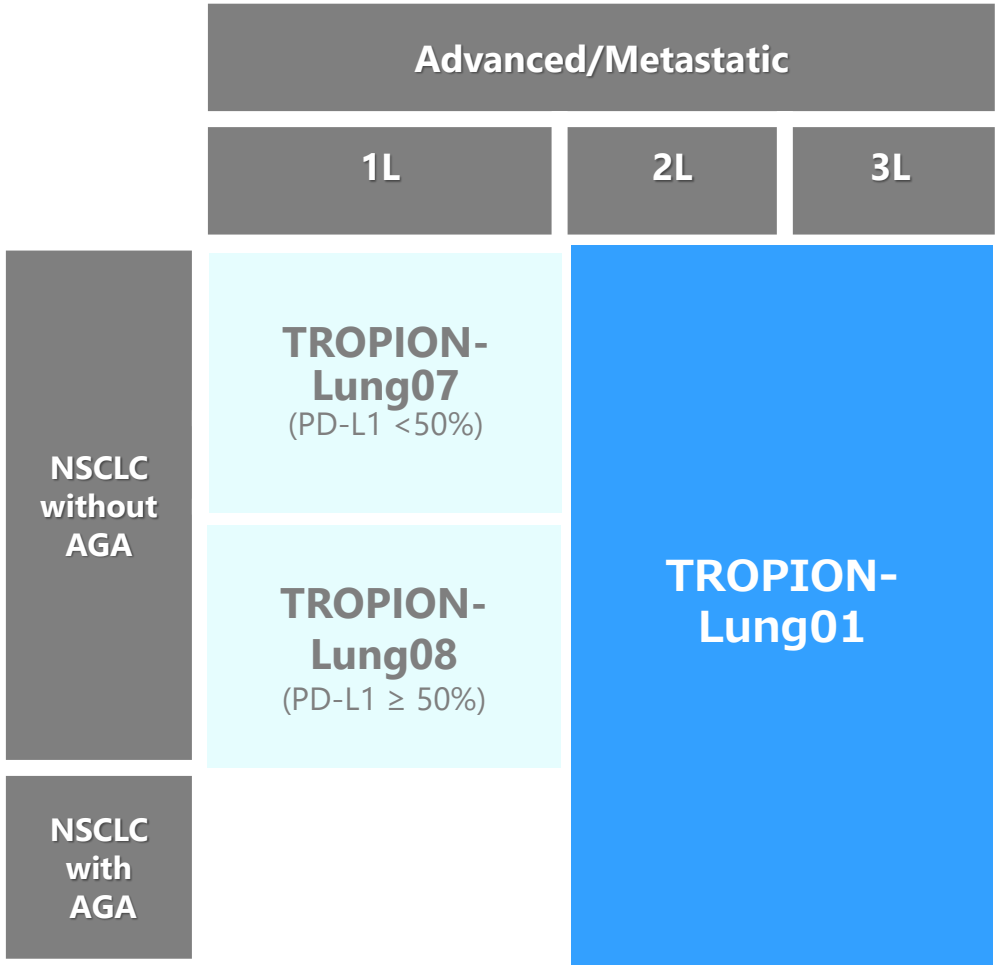
Randomization 1:1

- **Dato-DXd** 6.0 mg/kg
- **Docetaxel** 75 mg/m^2

Primary: PFS, OS
Secondary: ORR, DoR, DCR, PK, safety etc.

- Demonstrated statistically significant improvement in PFS
- No new safety signals identified, all grade ILD was generally consistent with prior clinical trials with the majority being grade1 or 2. Grade 5 ILD events were observed
- **Proceeding to file the data with FDA**

Major Ph3 Clinical Studies of Dato-DXd in NSCLC

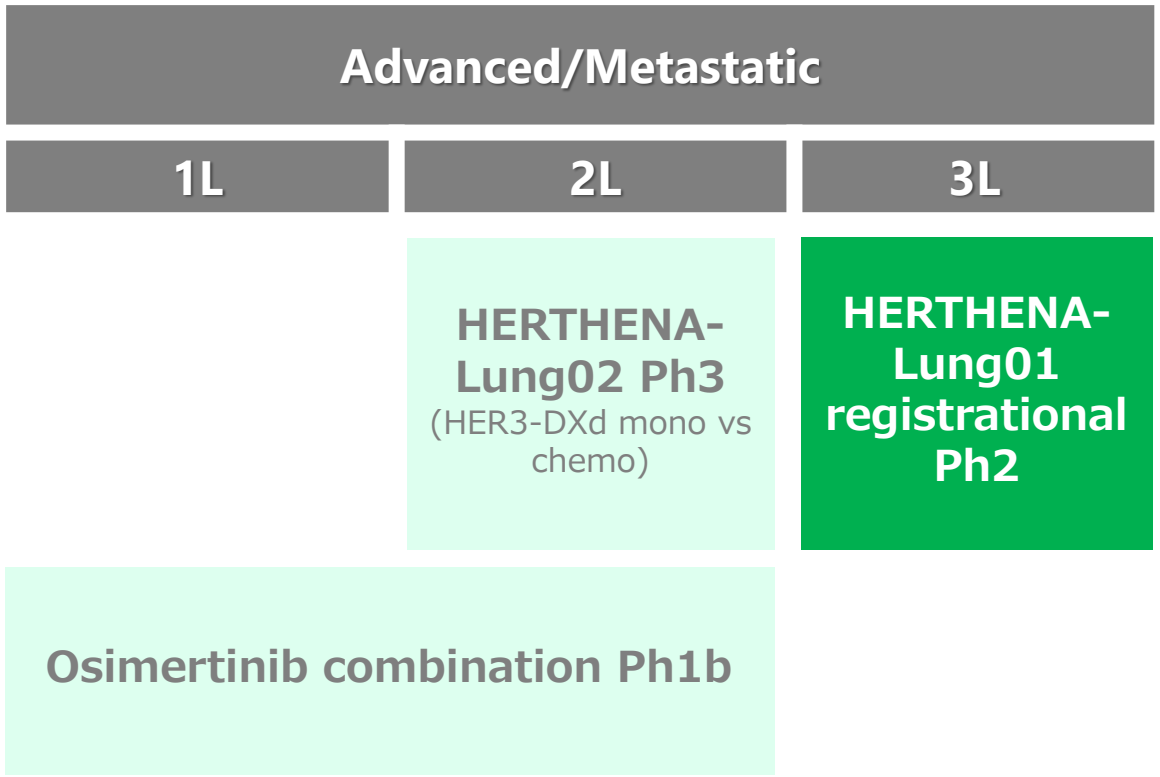


AGA: actionable genomic alteration, DCR: Disease Control Rate, DoR: Duration of Response, FDA: U.S. Food and Drug Administration, ILD: interstitial lung disease, NSCLC: Non-small Cell Lung Cancer, ORR: Overall Response Rate, OS: Overall Survival, PFS: Progression Free Survival, PK: Pharmacokinetics, TLR: Top Line Results

HER3-DXd HERTHENA-Lung01 study

Planned regulatory submission in US in FY2023 H2

Clinical studies of HER3-DXd in EGFR mutated NSCLC



- Announced the TLR outline in FY2022 Q4 earnings call
  - 5.6 mg/kg dose showed durable responses in patients with metastatic or locally advanced EGFR mutated NSCLC previously treated with an EGFR TKI and PBC
  - No new safety concerns identified
- Clinical data to be presented at **WCLC in Sep 2023**
- Other ongoing EGFR mutated NSCLC studies:
  - HERTHENA-Lung02 study (2L, Ph3)
  - Osimertinib combination Ph1b study

NSCLC: non-small cell lung cancer, PBC: platinum-based chemotherapy, TKI: tyrosine kinase inhibitor, WCLC: World Conference of Lung Cancer

5DXd-ADCs

Additional updates in clinical studies and regulatory communications

ENHERTU®

- Jun 2023: Combination study with DS-1103 (anti-SIRPα antibody) started
- Jul 2023: Approved in China for chemo treated HER2 low BC (DESTINY-Breast04)

DS-7300

- Apr 2023: Orphan drug designation granted by FDA for SCLC

BC: breast cancer, FDA: U.S. Food and Drug Administration, SCLC: small cell lung cancer

5DXd-ADCs Update

Next Wave Update

News Flow

Next Wave

New project: DS-3939 starts Ph1/2 study

DXd-ADC directed TA-MUC1 (DAR: 8)

Ph1/2 study in solid tumors is planned to start in FY2023 Q2

Ph1/2 Study Design

Dose Escalation Part
DS-3939 (IV, Q3W)

Locally advanced, metastatic, or unresectable NSCLC, BC, UC, OVC, BTC, or PDAC

→

Dose Expansion Part
DS-3939 (IV, Q3W)

Multiple expansion cohorts targeting various advanced solid tumors

Evaluate safety and preliminary efficacy

- DS-3939 is an ADC developed by combining an anti-TA-MUC1 antibody in-licensed from Glycotope GmbH (Berlin, Germany) and Daiichi Sankyo's DXd-ADC technology
- Tumor-associated Mucin 1 (TA-MUC1) is a transmembrane glycoprotein overexpressed in LC, BC, OVC, and other tumor types
- FIH study in solid tumors composed of dose escalation and dose expansion part is planned to start in FY2023 Q2

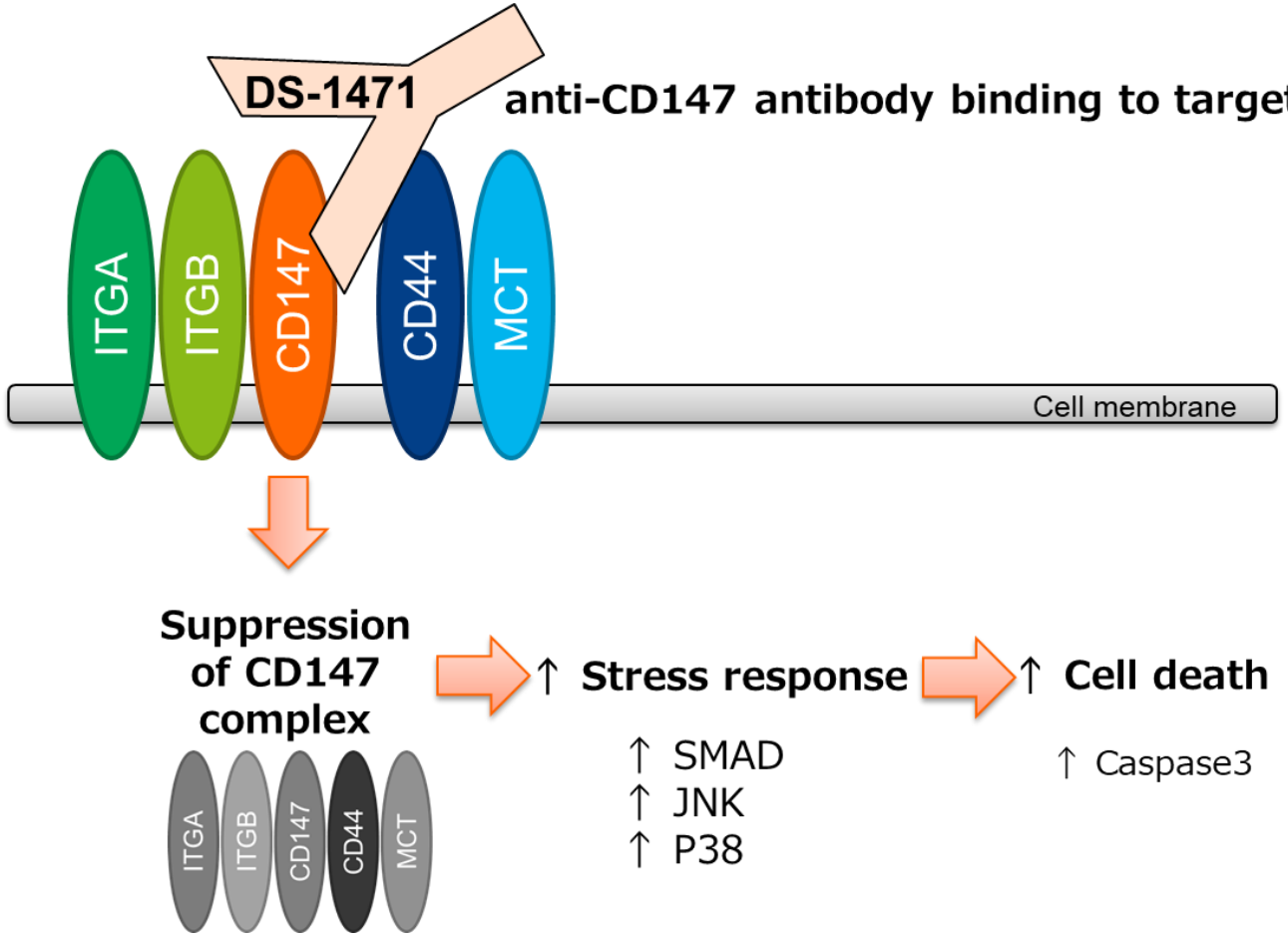
BC: breast cancer, BTC: biliary tract cancer, DAR: drug-antibody ratio, IV: intravenous, LC: lung cancer, NSCLC: non-small cell lung cancer, OVC: ovarian cancer, PDAC: pancreatic ductal adenocarcinoma, Q3W: every 3 weeks, UC: urothelial cancer

Next Wave

New project: DS-1471 starts Ph1 study

DS-1471 is a monoclonal antibody targeting CD147

Ph1 study for solid tumors is planned to start in FY2023 H2



- CD147 complex is important in survival, such as invasion and metastasis, in cancer tissues; also involved in embryogenesis and wound healing etc., in normal tissue
- Unique MoA by downregulation of CD147 complex leading to cellular stress response and apoptotic cell death
- FIH study composed of dose escalation and dose expansion in solid tumors will start FY2023 H2

FIH: first in human, MoA: mechanism of action

Next Wave

Clinical and Regulatory Progress

Vanflyta® (quizartinib) (*FLT3*-ITD positive acute myeloid leukemia [AML], 1L)

- May 2023: Approved in Japan
- Jul 2023: Approved in US

Ezharmia® (valemetostat) (relapsed/refractory peripheral T-cell lymphoma [PTCL])

- Jun 2023: TLR obtained

DS-5670 (COVID-19 mRNA vaccine)

- May 2023: Ph3 study for omicron strain booster vaccination in healthy volunteers 12 years and over
- May 2023: Ph2/3 study for omicron strain booster vaccination in children aged 5 to11 years

DS-7011 (systemic lupus erythematosus [SLE])

- Jul 2023: Ph1b/2 study for SLE patients started

DS-2325 (Netherton syndrome)

- May 2023: Granted Rare Pediatric Disease Designation by FDA

FDA: U.S. Food and Drug Administration, TLR: top line results

5DXd-ADCs Update

Next Wave update

News Flow

FY2023 News Flow

As of Jul 2023

Planned major publications

WCLC (Sep 9-12, 2023)

ENHERTU®	**DESTINY-Lung02: HER2 mutant NSCLC, 2L+, Ph2** • **Primary analysis data**
Dato-DXd	**TROPION-Lung04: NSCLC w/o AGA, 1L+, Ph1** • **Interim data**
HER3-DXd	**HERTHENA-Lung01: EGFR mutant NSCLC, 3L, Ph2** • **Primary analysis data**
DS-7300 (I-DXd)	**Ph1/2** • **SCLC sub-analysis data**

Regulatory decisions

ENHERTU®	DESTINY-Lung01, 02：HER2 mutant NSCLC, 2L+, Ph2 • JP: FY2023 Q2 • EU: FY2023 H2
VANFLYTA®	QuANTUM-First: AML, 1L, Ph3 • EU: FY2023 H2
DS-5670	**COVID-19 mRNA vaccine, original strain, booster vaccination, healthy adults, Ph1/2/3** • **JP: FY2023 Q2**

Key data readouts

ENHERTU®	DESTINY-Breast06*: HR+ and HER2 low BC, chemo naïve, Ph3 • **FY2023 H2**
Dato-DXd	TROPION-Breast01*: HR+ and HER2 low or negative BC, 2/3L, Ph3 • **FY2023 H2**

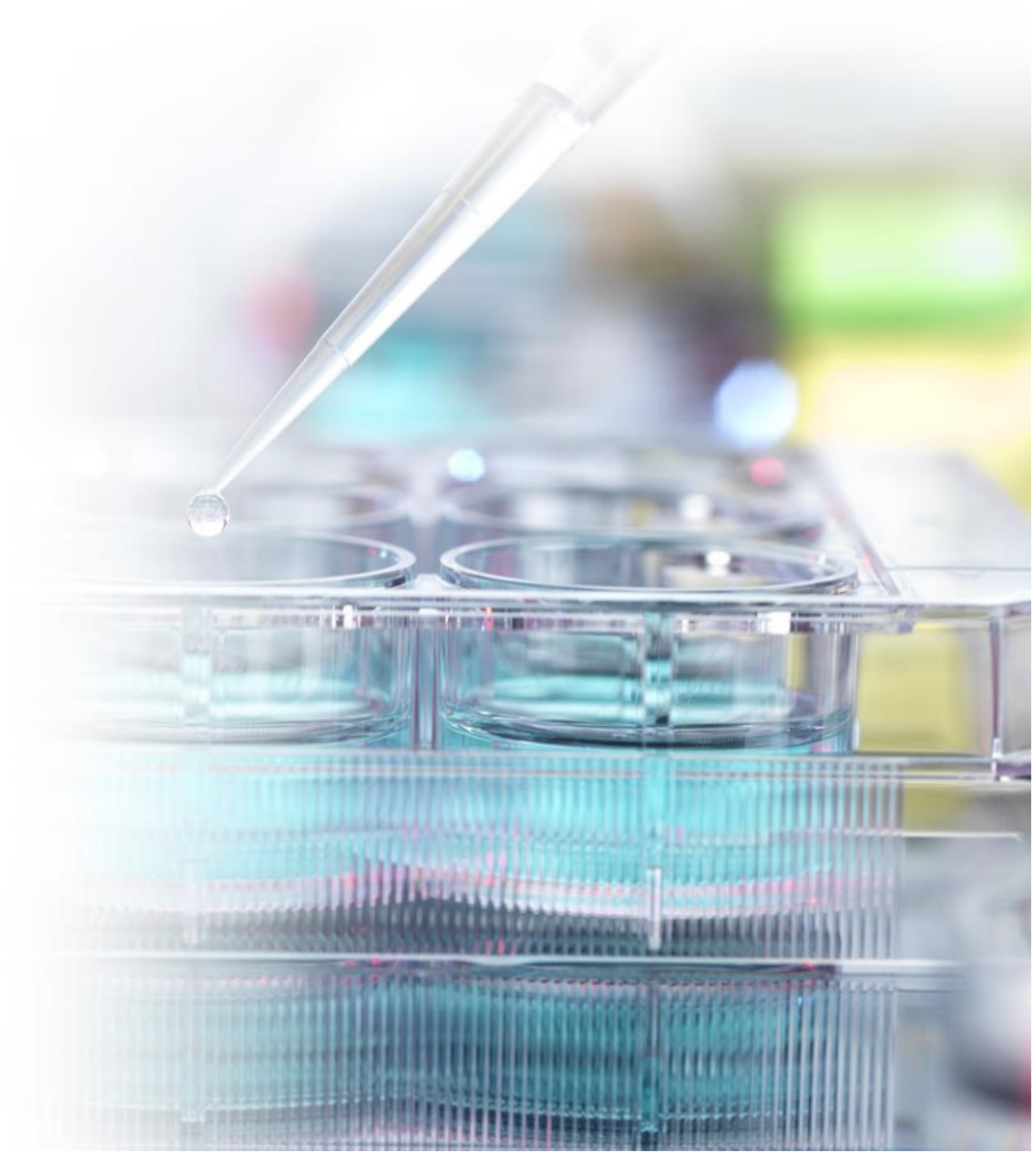
Bold: update from FY2022 Q4

AGA: actionable genomic alterations, AML: acute myeloid leukemia, BC: breast cancer, HR: hormone receptor, NSCLC: non-small cell lung cancer, SCLC: small cell lung cancer,
WCLC: World Conference on Lung Cancer

Timeline indicated is based on the current forecast and subject to change.
*Event-driven study

Agenda

1. FY2023 Q1 Financial Results
2. Business Update
3. R&D Update
4. **Appendix**



Major R&D Milestones (5DXd-ADCs ①)

As of Jul 2023

Project		Target Indication [phase, study name]	FY2023 H1	FY2023 H2	FY2024
ENHERTU®	BC	• HER2 low, post chemo [Ph3, DESTINY-Breast04]	**• Approved (China)**		
		• HER2 low, chemo naïve [Ph3, DESTINY-Breast06]		**• TLR anticipated**	
		• HER2+, 1L [Ph3, DESTINY-Breast09]			**• TLR anticipated**
		• HER2+, Neoadjuvant [Ph3, DESTINY-Breast11]			**• TLR anticipated**
	NSCLC	• HER2 mutant, 2L [Ph2, DESTINY-Lung01, 02]	• Approval anticipated (JP)	• Approval anticipated (EU)	
		• HER2 mutant, 1L [Ph3, DESTINY-Lung04]			**• TLR anticipated**

Bold: update from FY2022 Q4

BC: breast cancer, HR: hormone receptor, NSCLC: non-small cell lung cancer, TLR: top line results

※ Timeline indicated is based on the current forecast and subject to change

Major R&D Milestones (5DXd-ADCs ②)

As of Jul 2023

Project		Target Indication [phase, study name]	FY2023 H1	FY2023 H2	FY2024
Dato-DXd	NSCLC	• 2/3L [Ph3, TROPION-Lung01]	**• TLR obtained**		
	BC	• HR+ and HER2 low or negative BC, 2/3L [Ph3, TROPION-Breast01]		**• TLR anticipated**	
		• TNBC, 1L [Ph3, TROPION-Breast02]			**• TLR anticipated**
HER3-DXd	NSCLC	• EGFR mutated, 2L [Ph3, HERTHENA-Lung02]			**• TLR anticipated**
DS-7300 (I-DXd)	SCLC	• 2L [Dose optimization, Ph2]			**• TLR anticipated**

Bold: update from FY2022 Q4 BC: breast cancer, HR: hormone receptor, NSCLC: non-small cell lung cancer, SCLC: small cell lung cancer, TLR: top line results, TNBC: triple-negative breast cancer

※ Timeline indicated is based on the current forecast and subject to change

Major R&D Milestones (Next Wave)

As of Jul 2023

Project	Target Indication [phase, study name]	FY2023 H1	FY2023 H2	FY2024
VANFLYTA®	• AML, 1L [Ph3, QuANTUM-First]	**• Approved (JP/US)**	• Approval anticipated (EU)	
EZHARMIA®	• r/r PTCL [Registrational Ph2, VALENTINE-PTCL01]	**• TLR obtained**		
DS-1103	• HER2 expressing or mutant solid tumors, HER2 low BC [Ph1]	**• Study started**		
DS-3939	**• Solid tumors [Ph1/2]**	**• Study start planned**		
DS-1471	**• Solid tumors [Ph1]**		**• Study start planned**	
DS-7011	**• Systemic lupus erythematosus [Ph1b/2]**	**• Study started**		
DS-5670	• COVID-19 mRNA vaccine (mutant strain), booster vaccination [Ph3]	**• Study started**		
	• COVID-19 mRNA vaccine (original strain), booster vaccination [Ph1/2/3]	**• Approval anticipated (JP)**		

Bold: update from FY2022 Q4 AML: acute myeloid leukemia, BC: breast cancer, PTCL: peripheral T cell lymphoma, r/r: relapsed/refractory, TLR: top line results

※ Timeline indicated is based on the current forecast and subject to change

Major R&D Pipeline: 5DXd-ADCs

As of Jul 2023

Daiichi-Sankyo

Phase 1

- (US/EU/Asia) HER2+ BC 2L+/1L
  DESTINY-Breast07
- (US/EU/Asia) HER2 low BC
  Chemo naïve/ post chemo
  DESTINY-Breast08
- (JP/US/EU/Asia) HER2+ GC combo, 2L+/1L
  DESTINY-Gastric03
- (US/EU/Asia) HER2+ NSCLC
  (durvalumab combo) 1L
  DESTINY-Lung03
- (US/EU) BC, bladder
  (nivolumab combo)
- (US/EU) BC, NSCLC
  (pembrolizumab combo)
- (US/EU/Asia) solid tumors
  (AZD5305 combo)
  PETRA
- DS-7300 (JP/US)
  ESCC, CRPC, squamous NSCLC, SCLC, etc.
- DS-6000 (JP/US)
  Renal cell carcinoma, ovarian cancer
- (JP/US) solid tumors
  TROPION-PanTumor01
- (CN) NSCLC, TNBC
  TROPION-PanTumor02
- (JP/US/EU/Asia) NSCLC (w/o AGA,
  pembrolizumab combo)
  TROPION-Lung02
- (JP/US/EU) NSCLC (w/o AGA,
  durvalumab, AZD2936 and MEDI5752
  combo) TROPION-Lung04
- (JP/US/EU/Asia) solid tumors
  (AZD5305 combo)
  PETRA
- (JP/US/EU/Asia) NSCLC
- (JP/US) EGFR mutated NSCLC
  (osimertinib combo)
- (JP/US) HER3+ BC

Phase 2

- (US/EU/Asia) TNBC
  (durvalumab combo)
  BEGONIA
- (CN) HER2+ GC 3L
  DESTINY-Gastric06
- (CN) HER2 mutant NSCLC 2L+
  DESTINY-Lung05
- (US/EU/Asia) NSCLC
  (durvalumab combo) 2L+
  HUDSON
- (JP/US/EU) HER2+ CRC 3L
  DESTINY-CRC01
- (JP/US/EU/Asia) HER2+ CRC 3L
  DESTINY-CRC02
- (JP/US/EU/Asia)
  HER2 mutant tumor
  DESTINY-PanTumor01
- (US/EU/Asia)
  HER2 expressing tumor
  DESTINY-PanTumor02
- (JP/US/EU/Asia) solid tumors
  TROPION-PanTumor03
- (JP/US/EU/Asia) NSCLC (w/ AGA)
  TROPION-Lung05
- (US/EU/Asia) TNBC
  (durvalumab combo)
  BEGONIA
- (JP/US/EU/Asia) EGFR mutated
  NSCLC (osimertinib combo) 2L
  ORCHARD
- (US/EU/Asia) resectable early-stage
  NSCLC (durvalumab combo) neoadjuvant
  NeoCOAST-2
- (JP/US/EU/Asia) EGFR mutated
  NSCLC 3L
  HERTHENA-Lung01 ★
- DS-7300 (JP/US/EU/Asia)
  ES-SCLC ★

Phase 3

- (JP/US/EU/Asia) HER2+ BC
  adjuvant*1
  DESTINY-Breast05
- (JP/US/EU/Asia) HER2 low BC
  chemo naïve
  DESTINY-Breast06
- (JP/US/EU/Asia) HER2+ BC 1L
  DESTINY-Breast09
- (JP/US/EU/Asia) HER2+ BC
  neoadjuvant
  DESTINY-Breast11
- (US/EU/Asia) HER2 low BC,
  HER2 IHC 0 BC, 2/3L
  DESTINY-Breast15
- (JP/EU/Asia) HER2+ GC 2L
  DESTINY-Gastric04
- (JP/US/EU/Asia) NSCLC (w/ HER2 exon 19 or
  exon 20 mutation) 1L
  DESTINY-Lung04
- (JP/US/EU/Asia) NSCLC 2/3L
  TROPION-Lung01
- (JP/US/EU/Asia) non-squamous NSCLC (w/o
  AGA, pembrolizumab combo) 1L
  TROPION-Lung07
- (JP/US/EU/Asia) NSCLC (w/o AGA,
  pembrolizumab combo) 1L
  TROPION-Lung08
- (JP/US/EU/Asia) BC*2 2/3L
  TROPION-Breast01
- (JP/US/EU/Asia) TNBC 1L
  TROPION-Breast02
- (JP/US/EU/Asia) TNBC (mono or
  durvalumab combo) adjuvant*3
  TROPION-Breast03
- (JP/US/EU/Asia) EGFR mutated
  NSCLC 2L
  HERTHENA-Lung02

Filed

- (JP/EU) HER2 mutant NSCLC 2L+
  DESTINY-Lung01/Lung02 ⛨

ENHERTU® Dato-DXd HER3-DXd DS-7300 DS-6000

□ Project in oncology that is planned to be submitted for approval in some countries/regions based on the results of phase 2 trials

★ Breakthrough Designation (US) ⛨ Orphan drug designation (designated in at least one country/region among JP, US and EU)

*1 Adjuvant therapy for HER2 positive breast cancer patients with residual invasive disease following neoadjuvant therapy

*2 HR+, HER2 low or negative BC

*3 Adjuvant therapy for TNBC patients with residual invasive disease following neoadjuvant therapy

AGA: actionable genomic alterations, BC: breast cancer, CRC: colorectal cancer, CRPC: castration-resistant prostate cancer, ESCC: esophageal squamous cell carcinoma, ES-SCLC: extensive stage-small cell lung cancer, GC: gastric cancer, NSCLC: non-small cell lung cancer, SCLC: small cell lung cancer, TNBC: triple negative breast cancer

Major R&D Pipeline: Next Wave

As of Jul 2023

Phase 1	Phase 2	Phase 3	Filed
DS-1055 (JP/US) Anti-GARP antibody Solid tumors	Valemetostat (DS-3201)(JP/US/EU/Asia) EZH1/2 inhibitor PTCL	Pexidartinib (JP/Asia) CSF-1/KIT/FLT3 inhibitor Tenosynovial giant cell tumor	Quizartinib (EU) FLT3 inhibitor AML 1L
DS-1594 (US) Menin-MLL binding inhibitor AML, ALL	Valemetostat (DS-3201) (EU) EZH1/2 inhibitor BCL	Esaxerenone (JP) MR blocker Diabetic nephropathy	Mirogabalin (CN) α2δ ligands Diabetic peripheral neuropathic pain
DS-9606 (US/EU) Target undisclosed ADC Solid tumors	DS-1001 (JP) Mutant IDH1 inhibitor Glioma	VN-0102/JVC-001 (JP) Measles mumps rubella combined vaccine	DS-5670 (JP) COVID-19 mRNA vaccine (original strain) COVID-19 (booster vaccination)
DS-1103 Anti-SIRPα antibody HER2 expressing or mutant advanced metastatic solid tumors, HER2 low BC (ENHERTU® combo)	DS-1211 (US/EU) TNAP inhibitor Pseudoxanthoma elasticum	DS-5670 (JP) COVID-19 mRNA vaccine (original strain), COVID-19 (primary vaccination, 12 to 17 aged children)	
DS-3939 Anti-TA-MUC1 ADC Solid tumors (in prep.)	DS-5670 (JP) COVID-19 mRNA vaccine (mutant strain), COVID-19 (primary vaccination, 5 to 11 aged children) (in prep.)	DS-5670 (JP) COVID-19 mRNA vaccine (mutant strain) COVID-19 (booster vaccination, 12 years old and over)	
DS-1471 Anti-CD147 antibody Solid tumors (in prep.)	VN-0200 (JP) RS virus vaccine RS virus infection	DS-5670 (JP) COVID-19 mRNA vaccine (mutant strain), COVID-19 (booster vaccination, 5 to 11 aged children)	
DS-7011 (US) Anti-TLR7 antibody Systemic lupus erythematosus			
DS-2325 (US) KLK5 inhibitor Netherton syndrome			

Oncology

Specialty medicine

Vaccine

Project in oncology that is planned to be submitted for approval in some countries/regions based on the results of phase 2 trials

SAKIGAKE Designation (JP)

Orphan drug designation (designated in at least one country/region among JP, US and EU)

Rare Pediatric Disease Designation (US)

Fast Track Designation (US)

Breakthrough Designation (US)

ALL: acute lymphoblastic leukemia, AML: acute myeloid leukemia, BCL: B cell lymphoma, LBCL: large B cell lymphoma, PTCL: peripheral T-cell lymphoma

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